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Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF CALIFORNIA**  
**San Francisco Division**

ERIC TAYLOR AND KAYLA TAYLOR, )  
individually and on behalf of A.T. a minor; )  
K.T., a minor; T.T., a minor; and B.T., a )  
minor, Colorado residents, )

Plaintiffs,

vs.

FRESH EXPRESS INCORPORATED, a )  
Delaware corporation; and SAFEWAY, INC., )  
a Delaware corporation )  
Defendants. )

Case No.: \_\_\_\_\_

**COMPLAINT**

**DEMAND FOR JURY TRIAL**

Plaintiffs Eric Taylor and Kayla Taylor, individually and as parents and guardians of A.T., K.T., T.T., and B.T. (“the Taylors”), by and through their attorneys, Gruber Law Group and Pritzker Hageman, P.A., as and for their Complaint against Defendants, allege as follows:

## INTRODUCTION

1. This lawsuit arises out of life-altering injuries the Taylors sustained as a result of a fall of 2019 *E. coli* O157:H7 outbreak (“fall of 2019 outbreak”) involving adulterated romaine salad product that was processed, packaged, marketed, and sold by Defendants Fresh Express Incorporated (“Fresh Express”) and Safeway Inc. (“Safeway”).

2. This outbreak was caused by the same strain of *E. coli* that caused outbreaks in the fall of 2018, 2017, and 2016, and is the latest of more than 40 such *E. coli* outbreaks that have occurred since 2009.

3. Despite their knowledge and opportunity to prevent this latest *E. coli* outbreak, Defendants failed to ensure they and their suppliers used safe and sanitary growing, harvesting, processing, production, and manufacturing processes. Instead, Defendants misled consumers by suggesting their products and methods were safe. As a result of Defendants’ disregard for the health and safety of the salad-consuming public, Defendants are liable to the Taylors for consequential, statutory, and punitive damages.

## PARTIES

4. Plaintiffs Eric Taylor and Kayla Taylor are husband and wife, and are the parents and guardians of four minor children, A.T. (born xx-xx-2011), K.T. (born xx-xx-2009), B.T. (born xx-xx-2015) and T.T. (born xx-xx-2019). Eric Taylor and Kayla Taylor bring this action both in their individual capacities and as parents and guardians of their four children. All of the Plaintiffs reside in Grand Junction, Mesa County, Colorado, and are therefore Citizens of the State of Colorado. The four Taylor children are depicted in the following image:



5. Safeway is a corporation organized and existing under the laws of the State of Delaware, with its headquarters located in the City of Pleasanton, County of Alameda, State of California. Safeway is therefore a citizen and resident of Delaware and California.

6. Safeway is a retailer of food products, among other things, with stores located across the country, including Colorado. At all times material hereto, Safeway operated the grocery store located at 2901 F Rd. in Grand Junction, Colorado, from which Safeway sold the adulterated pre-packaged salad product at issue.

7. Fresh Express is a corporation duly organized and existing under the laws of the State of Delaware, with its headquarters located in the City of Windermere, State of Florida. Fresh Express is therefore a citizen and resident of Delaware and Florida.

8. Fresh Express grew, harvested, sourced, processed, manufactured, distributed, marketed, and sold the adulterated pre-packaged salad product at issue, through its intermediary, Safeway, which in turn sold the adulterated pre-packaged salad product at issue to the Taylors. Fresh Express maintains facilities and operations in California.

### **JURISDICTION AND VENUE**

9. This Court has jurisdiction over the subject matter of this action, pursuant to 28 U.S.C. § 1332, because there is diversity of citizenship and the amount in controversy is greater than \$75,000, exclusive of interests and costs.

1           10.     This Court has personal jurisdiction over the Defendants because Defendants  
 2 sourced, processed, manufactured, distributed, marketed, and/or sold salad products using  
 3 romaine lettuce grown in California, and because the Defendants have certain minimum contacts  
 4 with the State of California such that maintenance of the suit in this District does not offend  
 5 traditional notions of fair play and substantial justice. The causes of action alleged in this case  
 6 arise out of and relate to the Defendants' contacts with California.  
 7

8           11.     Venue is proper in the United States District Court for the District of California,  
 9 pursuant to 28 U.S.C § 1391(b)(2), because a substantial part of the events or omissions giving  
 10 rise to the Taylors' claims and causes of action occurred in this District, and because the  
 11 Defendants are subject to personal jurisdiction in this District at the time of the commencement  
 12 of this action.  
 13

#### 14                                   **INTRADISTRICT ASSIGNMENT**

15           12.     Assignment of this action to the San Francisco Division, pursuant to Civ. L.R. 3-  
 16 2(c) and (d), is appropriate because a substantial part of the events and omissions that gave rise  
 17 to this action occurred in Alameda County, California, which is where Safeway's corporate  
 18 offices are located. From its headquarters in Alameda County, Safeway arranged to purchase the  
 19 adulterated salad product at issue from Fresh Express and distribute and sell it in Safeway stores  
 20 across the country, including the Grand Junction, Colorado store from which the adulterated  
 21 salad product at issue was sold to the Taylors.  
 22

#### 23                                   **STATEMENT OF FACTS**

##### 24           **A.     *E. coli* O157:H7 and Hemolytic Uremic Syndrome**

25           13.     Shiga-Toxin producing *E. coli* ("STEC") is a bacterium that occurs in ruminant  
 26 animals and is shed in their feces. The most common and well-known STEC strain is *E. coli*  
 27 O157:H7.  
 28

1           14.     When *E. coli* O157:H7 or other STEC strains are ingested by humans, the bacteria  
2 causes an inflammatory response in the large intestine resulting in severe gastrointestinal  
3 symptoms such as bloody diarrhea and abdominal cramps.

4           15.     In the years since *E. coli* O157:H7 was first identified as a cause of diarrhea, this  
5 bacterium has established a reputation as a significant public health hazard. *E. coli* O157:17 is  
6 also notable among pathogenic bacteria for its extremely low infectious dose—that is, the  
7 number of bacteria necessary to induce infection in a person. Even a microscopic amount of  
8 exposure can trigger a devastating infection.

9           16.     *E. coli* O157:H7 infections can also cause life-threatening complications  
10 including kidney damage and Hemolytic Uremic Syndrome (“HUS”). HUS has three central  
11 features: destruction of red blood cells, destruction of platelets (those blood cells responsible for  
12 clotting), and acute renal failure due to the formation of micro-thrombi that occlude microscopic  
13 blood vessels that make up the filtering units within the kidneys.

14           17.     HUS accounts for the majority of the acute and chronic illnesses and deaths  
15 caused by the bacteria. HUS occurs in two to seven percent of victims, primarily children and  
16 immune-compromised adults, with onset five to ten days after diarrhea begins.

17           18.     There is no cure or effective treatment for HUS. Once HUS develops, there is a  
18 very real risk of death or permanent kidney damage.

19           19.     Other long-term problems following HUS include an increased risk for  
20 hypertension, proteinuria (abnormal amounts of protein in the urine that can portend a decline in  
21 renal function), and reduced kidney filtration rate.

22           20.     In short, HUS causes permanent injury, including loss of kidney function, and it  
23 requires a lifetime of close medical monitoring.  
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1           21.     Some patients with HUS show central nervous system involvement often leading  
2 to neurological symptoms including seizures, stupor or coma, pyramidal syndrome, hemiplegia  
3 or hemiparesia, extrapyramidal syndrome, and cognitive dysfunction.

4           22.     Because of the severe health risks and the significant public health costs posed by  
5 *E. coli* O157:H7, the Centers for Disease Control (“CDC”) along with state and local health  
6 departments actively monitor these cases to identify the source of illness-causing foods and stop  
7 outbreaks.

8           23.     State and CDC labs routinely perform sophisticated testing on *E. coli* O157:H7  
9 samples, including genetic subtyping processes such as Pulsed-Field Gel Electrophoresis  
10 (“PFGE”). PFGE results—akin to genetic fingerprints—are then loaded into a national database  
11 where they are easily compared to one another.

12           24.     In addition to PFGE testing, public health officials can also perform whole  
13 genome sequencing (“WGS”) on samples.

14           25.     WGS in combination with PFGE testing allows public health officials to more  
15 definitively link illnesses to a common source. This system alerts state departments of health and  
16 the CDC when the number of STEC cases spike or when a group of cases are caused by the  
17 same, or a closely related, genetic strain of the bacteria. The CDC and health departments then  
18 investigate those cases as a single-source outbreak.

19  
20  
21 **B.     Common Sources of *E. coli* Contamination**

22           26.     Cattle have long been known as a primary reservoir for *E. coli* O157:H7 and other  
23 STECs, and have been implicated as the original source of the bacteria in many of the outbreaks  
24 described in the chart set forth in paragraph 105 below.

1           27. Cattle excrete *E. coli* O157:H7 and other STECs in manure; consequently, given  
2 the number of cattle at any Concentrated Animal Feeding Operations (“CAFOs”), they are a  
3 significant source of pathogenic bacteria and other contaminants and pollutants.

4           28. In fact, the most pressing public health issue associated with CAFOs stems from  
5 the amount of manure they produce. In addition to pathogenic bacteria, cattle manure and other  
6 wastes also contain growth hormones, antibiotics, chemicals used as additives to the manure or  
7 to clean equipment, animal blood, silage leachate from corn feed, or copper sulfate used in  
8 footbaths for cows.

9  
10           29. As a result of the manure and other wastes generated at CAFOs, they attract and  
11 harbor large numbers of insects, vermin, and other wildlife, which become mechanical vectors  
12 for the transmission of pathogens and other of the aforementioned pollutants to locations beyond  
13 the borders of the CAFOs.

14  
15           30. Dried manure and particulate matter generated at CAFOs can be and is blown by  
16 wind over nearby vegetation and open water sources, and is a mechanical vector for the  
17 transmission of pathogens and other pollutants to locations beyond the borders of the CAFOs.

18           31. Manure runoff generated at CAFOs can and does migrate to nearby water sources,  
19 and is a mechanical vector for transmission of pathogens and other pollutants to locations beyond  
20 the borders of the CAFOs.

21  
22           32. The leafy greens industry, including grower-shippers and processors nationally, in  
23 conjunction with academicians and scientists in relevant disciplines, has long recognized the  
24 threat that CAFOs pose to fresh vegetables grown nearby that are intended to be consumed raw.

25           33. The Salinas growing region is surrounded by CAFOs.  
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34. Other potential contamination sources include wild animals, grazing ruminant animals, housing developments, and other human encroachment. Feces from these sources can contaminate lettuce with STEC through the same or similar mechanical vectors as CAFOs.

35. The leafy greens industry, including grower-shippers and processors nationally, in conjunction with academicians and scientists in relevant disciplines, has long recognized the threat that wild animals, grazing ruminant animals, housing developments, and other human encroachment poses to fresh vegetables grown nearby that are intended to be consumed raw.

**C. Standards Applicable to Growers, Processors, Distributors, Retailers, and Others**

**i. *Water Standards***

36. Food safety dangers and outbreaks associated with water use in crop production have long been or should have been known by the entities in the chain of distribution of the adulterated romaine lettuce responsible for the outbreak in question, including the Defendants.

37. Dating back to the 1990s, research has shown that the use of contaminated agricultural water can increase the frequency of pathogen isolation from harvested produce.

38. In response to water quality issues, among others, in October 1998, the Food and Drug Administration (“FDA”) issued a “Guidance for Industry” entitled “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables.” It noted, “Water of inadequate quality has the potential to be a direct source of contamination and a vehicle for spreading localized contamination in the field, facility, or transportation environments. Whenever water comes in contact with fresh produce, its quality dictates the potential for pathogen contamination. If pathogens survive on the produce, they may cause foodborne illness.”

39. The FDA’s October 1998 Guide listed a number of considerations to reduce the risk of foodborne illness resulting from the use of unsafe agricultural water. Among them was the need to consider water quality and use. The guide recommends, “To the extent feasible,



1 growers should follow good agricultural practices that minimize the potential for contaminated  
2 water to contact the edible portion of the crop.”

3 40. The Guide also states, “Water quality should be adequate for its intended use.  
4 Where water quality is unknown or cannot be controlled, growers should use other good  
5 agricultural practices to minimize the risk of contamination.”

6 41. On February 5, 2004, and November 4, 2005, the FDA Center for Food Safety  
7 and Applied Nutrition issued letters to the California lettuce and leafy green industry intended to  
8 make the industry aware of the FDA’s serious concern with the continuing outbreaks associated  
9 with the consumption of fresh and fresh-cut lettuce and other leafy greens.

10 42. These letters encouraged firms in the lettuce and leafy green industry to review  
11 their current operations in light of guidance and information regarding the reduction or  
12 elimination of pathogens on fresh produce, and modify their operations to ensure they were  
13 taking appropriate measures to provide safe product to consumers.

14 43. In April 2006, members of the lettuce and leafy greens industry, including the  
15 International Fresh-Cut Produce Association, Produce Marketing Association, United Fresh Fruit  
16 and Vegetable Association, and the Western Growers, issued the First Edition of the Commodity  
17 Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain. According to  
18 its authors, “This document provides voluntary recommended guidelines on food safety practices  
19 that are intended to minimize the microbial hazards associated with fresh and fresh-cut  
20 lettuce/leafy greens products. The intent of drafting this document is to provide currently  
21 available information on food safety and handling in a manner consistent with existing  
22 applicable regulations, standards and guidelines...”

23 44. The First Edition of these Guidelines included the following “Things to  
24 Consider”:  
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- a. Assuring that irrigation water and water used in harvest operations is of appropriate microbial quality for its intended use.
- b. Reducing human pathogen contamination of soil which may in turn contaminate water and/or edible portions of lettuce and leafy greens (*e.g.*, solarization, fumigation, etc.).
- c. Evaluating irrigation methods (drip irrigation, overhead sprinkler, furrow, etc.) for their potential to introduce, support, or promote the growth of human pathogens on lettuce and leafy greens. Considerations include the potential for depositing soil on the crop, pooled, or standing water that attracts animals, etc.
- d. Evaluating irrigation water reservoir conditions and means of reducing, controlling, or eliminating potential contamination with human pathogens.
- e. Evaluating risks of using tail water and/or reclaimed (primary or secondary) water, including use in operations such as road dust abatement.
- f. When waters from various sources are combined, consider the potential for pathogen growth.
- g. Using procedures for storing irrigation pipes and drip tape that reduce potential pest infestations. Developing procedures to assure safe use of irrigation pipes and drip tape if a pest infestation does occur.
- h. Water used for direct or indirect application to edible portions of lettuce/leafy greens such as spraying and mixing pesticides should be of appropriate microbial quality for its intended purpose. Water may be tested on a regular basis, treated or drawn from an appropriate source as a means of assuring it is appropriate for its intended purpose.
- i. Water used on harvesting equipment or during harvesting should be of appropriate microbial quality for its intended use (*e.g.*, meets U.S. Environmental Protection Agency or World Health Organization microbial standards for drinking water). The water source should be tested periodically to assure that it is of appropriate microbial quality for its intended purpose.

45. In the fall of 2006, there was a massive *E. coli* O157:H7 outbreak involving spinach salad greens. Two hundred and five people were sickened and there were three deaths.

46. The fall of 2006 outbreak was likely caused, in whole or in part, by agricultural water of unsafe sanitary quality.

47. Following the fall 2006 outbreak, the Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain were updated periodically, including

1 editions issued in 2007, 2010, 2011, 2012, and 2013, among others. With regard to water safety  
2 issues, each new edition set forth current “best practices” for fresh and fresh-cut lettuce and leafy  
3 green products.

4 48. These “best practices” apply not just to growers; they apply to all entities in the  
5 farm-to-fork supply chain. For example, in the 2011 Edition, the Guideline states: “All  
6 companies involved in the lettuce/leafy greens farm to table supply chain shall implement the  
7 recommendations contained within these guidelines to provide for the safe production and  
8 handling of lettuce/leafy greens products from fields to fork. Every effort to provide food safety  
9 education to supply chain partners should also be made...”

10  
11 49. The Guidelines described above were not the only standards for Good  
12 Agricultural Practices (“GAPs”) in effect prior to the outbreak in question. For example, in 2003,  
13 The Code of Hygienic Practice for Fresh Fruits and Vegetables was adopted by the Codex  
14 Alimentarius Commission, a body established in 1963 by the World Health Organization. The  
15 objectives of this code are addressed as follows:  
16

17 This Code addresses Good Agricultural Practices (GAPs) and Good  
18 Hygienic Practices (GHPs) that help control microbial, chemical and  
19 physical hazards associated with all stages of the production of fresh fruits  
20 and vegetables, from primary production to consumption. Particular  
21 attention is given to minimizing microbial hazards. The Code provides a  
22 general framework of recommendations that can be uniformly adopted  
23 across the sector rather than detailed recommendations for specific  
24 agricultural practices, operations or commodities.

25 50. In Section 3.2.1.1, the Code describes in great detail the considerations and  
26 actions required for suitable water quality for primary fruit and vegetable production. These  
27 duties include identification of the sources of water used, use of further treatment to assure  
28 safety, assessment of the water quality, testing for the presence of pathogens, frequency of  
testing, reassessment of water quality if underlying conditions change, etc.

51. Section §3.2.1.1.1 of the Code addresses water for irrigation and harvesting. It, too, lists specific duties required for safe irrigation water. This section concludes as follows:

Water for agricultural purposes should be of suitable quality for its intended use. Special attention should be given to water quality in the following situations:

- Irrigation by water-delivery techniques that expose the edible portion of fresh fruits and vegetables directly to water (*e.g.* sprayers), especially close to harvest time;
- Irrigation of fruits and vegetables that have physical characteristics such as leaves and rough surfaces that can trap water; and
- Irrigation of fruits and vegetables that will receive little or no post-harvest wash treatments prior to packing, such as field-packed produce.

Additionally, growers, where appropriate, should:

- Evaluate the water-distribution system to determine if a contamination source is evident and can be eliminated; and
- Establish no-harvest zones if irrigation source water is known or likely to contain human pathogens and where failure at connections results in overspray of plants or localized flooding.

52. Following a large STEC outbreak linked to romaine lettuce in the spring of 2010, the FDA issued an Environmental Assessment dated December 29, 2010, which emphasized:

The importance of using water of adequate quality for its intended use to ensure safety, particularly for applications that will likely contact the edible portion of the plant, and [] the importance of producers having knowledge about their water source and potential sources of contamination that influence the sanitary quality of that water.

53. In addition, the Environmental Assessment listed preventive control strategies “that may help to reduce the possibility of future contamination and outbreaks that relate to the specific circumstances associated with this environmental assessment...” Among the potential preventive control strategies listed in the FDA’s December 29, 2010, Environmental Assessment are the following:

- a. Assessing and documenting potential sources of runoff likely to cause irrigation water contamination.

- b. Developing and implementing microbiological monitoring protocols water systems, particularly in times of increased precipitation or abnormal water events.
- c. Conducting sanitary surveys of the water source and distribution system for water used in produce production operations at the beginning of the production season and after any changes in practices and conditions.
- d. Monitoring of water quality by growers and harvesters during and after a precipitation event.
- e. Conducting a microbiological survey of agricultural waters.

54. In an article published by the CDC's Environmental Health Services Branch in 2012, seven years before the outbreak at issue in this case, the article's authors observed:

[T]he quality of irrigation water can have profound impacts on the microbiological integrity of food... Many sources of irrigation water are subject to inputs of pathogenic loads from point and nonpoint sources stemming from multiple land uses in watersheds.... A systems-based, watershed scale analysis is necessary for comprehensive identification of factors potentially contributing to irrigation water contamination... Such an approach would include a systematic identification of risks to irrigation water quality, both within an irrigation system as well as in the broader watershed environment, and could help to identify and prevent contamination of produce from irrigation water.

55. While not yet mandatory, 21 C.F.R. § 112, Subpart E establishes certain Produce Safety Rules to reasonably ensure produce is not adulterated by agricultural water of inadequate sanitary quality for its intended use.

56. Since these water quality Produce Safety Rules were promulgated in 2016, their compliance dates have been extended due to lobbying from the lettuce and leafy green industry.

57. The Produce Safety Rules in Subpart E requires growers to, among other things, inspect their agricultural water systems "to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce ..."; to ensure there is no detectable *E. coli* in 100 milliliters of agricultural water, and to not use untreated surface water for certain purposes; and to establish and keep records regarding inspection of

1 agricultural water systems, test results, and scientific data relied upon in evaluating agricultural  
2 water.

3 58. At all times material herein, Fresh Express was and remains a member of and  
4 signatory to the California Leafy Green Shipper Marketing Agreement (“CA-LGMA”).

5 59. The CA-LGMA program was first became effective in February 2007.

6 60. Although the CA-LGMA program is voluntary, the requirements therein are  
7 mandatory for all signatories, including Fresh Express.

8 61. Signatories of the CA-LGMA, including Fresh Express, must comply with the  
9 current versions of best practices set out in the “Commodity Specific Food Safety Guidelines for  
10 the Production and Harvest of Lettuce and Leafy Greens.”

11 62. The Commodity Specific Guidelines for lettuce and leafy greens contain best  
12 practices, including but not limited to the following:

- 13 a. Evaluate all produce fields for evidence of animal hazards and/or feces.
  - 14 b. Evaluate all land and waterways adjacent to all production fields for  
15 possible sources of human pathogens of concern.
  - 16 c. Conduct a rigorous pre-season environmental assessment of any CAFOs  
17 that may impact operations, and communicate with CAFO operators to  
18 document Best Management Practices (“BMPs”) within CAFO facilities.
  - 19 d. Evaluate agricultural water systems to ensure that the quality of  
20 agricultural water used in leafy green operations is known and adequate  
21 for its intended use.
  - 22 e. Use water that is of appropriate microbial quality for its intended use.
  - 23 f. Test water routinely, and take appropriate remedial and corrective actions  
24 if microbial levels are above specific action levels, and retest to confirm  
25 the efficacy of remedial and corrective actions.
  - 26 g. Where fecal contamination is likely, treat agricultural water and test the  
27 water whenever water systems are in use.
- 28

63. In addition, CA-LGMA signatories, including Fresh Express, may only buy, consign, or otherwise accept or handle leafy green products from a shipper or producer who also is in compliance with the best practices (including record keeping requirements), maintains a traceback system, and is subject to periodic audit.

64. As specified by the CA-LGMA, “LGMA members must be in 100 percent compliance with all of the LGMA food safety practices in order to be certified. The LGMA requires that members take corrective action on any and all findings cited during government audits and that preventive measures are in place to protect public health.”

65. In addition to being a signatory of the CA-LGMA, Fresh Express also is and was a member of and signatory to the Arizona Leafy Green Products Shipper Marketing Agreement (“AZ-LGMA”) that were first implemented in October 2007.

66. Although the AZ-LGMA program is voluntary, the requirements contained therein are mandatory for all signatories, including Fresh Express.

67. The AZ-LGMA has requirements that are the same or substantially similar to those in the CA-LGMA, as set forth above.

68. In addition to the mandatory duties and responsibilities imposed on Fresh Express as a signatory of both the CA- and AZ-LGMAs, Fresh Express advertised and promoted its purported commitment to food safety. According to its website:

What does Fresh Express do to assure salads are safe?

At Fresh Express, food safety is our number one priority throughout our entire company. We believe strongly that you have the right to expect salads that are fresh and safe. Our food safety requirements begin right in the field with growing and harvesting practices and continue all the way through until our salads reach your grocer.

We meet – and in numerous instances exceed – the food safety requirements established by government – and have for the past several years. Although we are recognized for our leadership in food safety, we would never rest on our past laurels or successes. We have a program in place to continuously evaluate all of

1 our food safety practices to make sure they're as strong as they can be and  
2 working effectively. For food safety and freshness, you can count on Fresh  
Express.

3 69. Fresh Express's website also includes the following representations regarding the  
4 safety of its salad products:

5 Food Safety is one of our top priorities. We're very proud that our safety practices  
6 have become widely recognized throughout the food industry.

7 1. Excellence Before Everything

8 Before the first seed is even planted, sound food safety and Good Agricultural  
9 Practices are already in place. Our growers and harvesters must meet the high  
10 standards we have developed for growing and field practices, irrigation and water  
quality, resource management, sanitation, harvesting and much more.

11 2. Reap the Best

12 Each year our Food Safety specialists inspect crop fields, complete individual  
13 audit surveys and conduct many, many product safety reviews. Audits may be  
14 conducted prior to growing, and during production and harvest.

15 \*\*\*

16 4. Train & Educate in Food Safety

17 At Fresh Express, we are firm believers that continual training and ongoing  
18 education at all levels are critical to food safety vigilance. Our employees attend  
and conduct training sessions and seminars every year on food safety and quality.  
19 We also conduct special sessions for our alliance of growers to ensure they are  
adept at all of our enhanced requirements and that their teams and crews are  
20 equally prepared to fulfill their food safety obligations each and every day.

21 Our large food safety and quality team of professionals includes food scientists,  
22 agronomists, soil scientists and other experts. They work throughout our  
processes to ensure that our efforts stay at the forefront of food safety  
23 excellence....

24 70. The Global Food Safety Initiative ("GFSI") allows food companies to become  
25 certified to food safety standards recognized by GFSI.

26 71. One GFSI recognized standard is SQF Food Safety Code for Primary Production,  
27 Edition 8, the code edition in effect at the time of the outbreak at issue.  
28



72. The SQF primary production code has specific provisions for water and land use risk assessments, including the following:

7.1.1.2 Production and growing sites shall have a risk assessment conducted to evaluate and document the risk to crops due to prior land use, adjacent land use, and other environmental factors ....

7.1.1.4 Where risks are identified, control measures shall be implemented to reduce the identified hazards to an acceptable level....

7.5.2.1 Agricultural water shall be drawn from a known clean source or treated to make it suitable for use. The producer shall conduct an analysis of the hazards to the irrigation water supply from source through to application, establish acceptance criteria for the monitoring of water and validate and verify the integrity of the water used to ensure it is fit for the purpose....

7H.1.1.2 When land use history or adjacent land use indicates a possibility of physical, chemical or biological contamination, preventive controls shall be performed and documented to mitigate food safety risk....

7H.1.1.3 The assessment is re-performed, and documented, at least annually for environmental conditions or risk awareness that has changed since the last assessment....

7H.3.1.5 Water used with agricultural chemicals shall not be a source of product or field contamination. Water used to dilute or deliver agricultural chemicals shall be from a source in compliance with the water system risk assessment and water management plan, consistent with current industry practices or regulatory requirements for that commodity.....

73. Despite the specific and science-based best practices for water safety, including irrigation water, as set forth in the foregoing GAPs, codes, and guidelines, each of the Defendants failed and refused to follow these best practices and/or ensure their suppliers followed them. These failures, up and down the supply chain involving each of the Defendants, were a direct cause of the adulteration of the salad products implicated in this outbreak.

74. These long-standing failures, which are contrary to its public representations and assurances, are violations of the Defendants' food safety obligations and are a direct cause of the illness and damages suffered by the Taylors.

1           **ii.     *Processing and Distribution Standards***

2           75.     Food safety dangers and outbreak risks associated with fresh-cut vegetables  
3 and/or fresh-cut produce have long been or should have been known by the entities in the chain  
4 of distribution for the adulterated romaine lettuce responsible for the outbreak at issue, including  
5 the Defendants.

6  
7           76.     Fresh-cut vegetables and/or fresh-cut produce, as processed by companies such as  
8 Fresh Express, are fresh fruits and vegetables for human consumption that have been minimally  
9 processed and altered in form by slicing, chopping, shredding, coring, or trimming, with or  
10 without washing, prior to being packaged for use by the consumer or a retail establishment (*e.g.*,  
11 pre-cut, packaged, ready-to-eat salad mixes).

12           77.     Processing fresh produce into fresh-cut products increases the risk of bacterial  
13 growth and contamination by breaking the natural exterior barrier of the produce. The release of  
14 plant cellular fluids when produce is chopped or shredded provides a nutritive medium in which  
15 pathogens, if present, can survive, grow, and spread.

16  
17           78.     Proper sanitation procedures prevent the presence, survival, growth, and spread of  
18 pathogens during fresh-cut processing. Inversely, the absence of proper sanitation increases the  
19 risk of pathogen contamination.

20           79.     The process of mixing (*i.e.*, comingling) raw produce common to many fresh-cut  
21 processing operations can cause pathogen contamination to spread to other lettuce products that  
22 were not previously adulterated.

23  
24           80.     Pathogenic microorganisms may also be spread by equipment in the plant  
25 processing environment, including on food preparation surfaces, utensils, and machines used to  
26 process the lettuce, resulting in the further spread of dangerous organisms such as *E. coli*  
27 O157:H7.  
28

1           81.     The same process of mixing, processing, and comingling romaine lettuce from  
2 various farms and then packaging it together also makes traceback investigations difficult or  
3 impossible, unless each party in the chain of distribution maintains suitable records that track the  
4 movement of the product and all its ingredients from farm to fork.

5           82.     In February of 2008 the FDA issued a guidance document directed at processors  
6 of fresh-cut produce, including romaine lettuce, entitled “Guidance for Industry: Guide to  
7 Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables.”  
8

9           83.     In the its 2008 fresh-cut Guidance, the FDA recommended “the following  
10 practices to ensure that incoming fresh produce is safe and suitable for processing into fresh-cut  
11 product:

- 12           a.     Becoming aware of practices used by your suppliers (*i.e.*, growers,  
13                 packers, coolers, transporters, etc.);
- 14           b.     Evaluating the practices of your suppliers by a knowledgeable food safety  
15                 expert;
- 16           c.     Accepting produce from suppliers who use GAPs, [Good Manufacturing  
17                 Practices (“GMPs”)] or other appropriate practice from the farm to the  
18                 processing facility; and
- 19           d.     Using a mechanism to verify the use of food safety practices by your  
20                 suppliers (e.g., letter of certification or guarantee from a supplier).”

21           84.     The FDA’s 2008 fresh-cut Guidance also recommends that food  
22 processors should maintain records sufficient to reflect important product information  
23 and practice, including water quality and supply records, water treatment and monitoring  
24 records, product processing batch records, distribution records, and microbiological  
25 contamination records.

26           85.     The 2008 fresh-cut Guidance notes that “use of package and date codes  
27 can help link product packages with production times, equipment, raw ingredients  
28

1 sources and may facilitate recovery of products during a recall.... Produce growers and  
 2 packers, fresh-cut produce processors, and shippers are encouraged to work with their  
 3 partners in growing, transporting, distributing, packing, and processing, and with retail  
 4 sectors to develop technologies that allow identification of fresh-cut produce from the  
 5 grower to your operation, to the retailer, and to the consumer.”

6  
 7 86. Despite the 2008 fresh-cut Guidance’s specific and science-based best  
 8 practices for processors of fresh-cut fruits and vegetables, issued more than a decade  
 9 before the outbreak at issue, Fresh Express and Safeway failed to and/or refused to  
 10 properly follow and require suppliers to follow these Guidelines. These failures, up and  
 11 down the supply chain involving each of the Defendants:

- 12 a. Were a direct cause of the adulteration of the romaine lettuce implicated in  
 13 this outbreak;
- 14 b. Made traceback of adulterated romaine lettuce from farm-to-table  
 15 needlessly difficult and time consuming;
- 16 c. Prevented identification and remediation of hazards that caused the  
 17 adulteration at issue before the fall of 2019 outbreak occurred; and
- 18 d. Otherwise made it impossible to detect and prevent the microbial  
 19 contamination that resulted in the outbreak at issue in this case.

20 87. In or before 2008 and continuing to the present, fresh-cut romaine lettuce was and  
 21 is considered by the FDA to be “processed food” and therefore subject to the GMP requirements  
 22 for foods set forth in 21 C.F.R. Part 110.

23 88. These requirements applied to Fresh Express, as the processor of the salad  
 24 product sold by Safeway and consumed by members of the Taylor family.

25 89. Fresh Express’s conduct as set forth in this Complaint and as identified in further  
 26 discovery, is in violation of the requirements set forth in 21 C.F.R. Part 110.  
 27  
 28

90. As a direct result of Fresh Express's conduct as set forth in this Complaint and as identified in further discovery, consisting of but not limited to violations of the requirements set forth in 21 C.F.R. Part 110, the salad product grown and processed by Fresh Express, sold by Safeway, and consumed by members of the Taylor family, was adulterated within the meaning of Sections 402(a)(3) and 402(a)(4) of the Act.

91. Despite these failures, for many years, Fresh Express also advertised and promoted its commitment to food safety in its processing operations. According to its website Fresh Express claimed:

### 3. Pack in Prevention

All of our leafy greens are carefully and thoroughly washed, blended and prepared using our custom processes....

Just as in growing the crop, prevention is a primary focal point in our facilities. We meticulously adhere to follow FDA's Food Safety Modernization Act requirements including Current Good Manufacturing Practices and principles of HACCP (Hazard Analysis and Critical Control Points). Our rigorous system is designed to prevent and mitigate against potential problems during the entire salad-making process.

Our quality team conducts food safety and quality tests in our salad facilities. In fact, we perform multiple tests all day long. We are also evaluated by third-party auditors to ensure our high standards.

92. The SQF Food Safety Code for Manufacturing is among the GMPs applicable to salad product processors and manufacturers. Edition 8.0, the code edition in effect at the time of the outbreak at issue, has specific provisions for raw materials and ingredients, including the following:

2.3.2.4 Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, or certificate of analysis, or sampling and testing....

2.4.3.8 The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

2.4.3.9 The food safety team shall conduct a hazard analysis for every identified hazard, to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards....

2.4.3.11 Based on the results of the hazard analysis (refer to 2.4.3.9), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e. a critical control point, or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

2.4.3.12 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard(s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).

2.4.3.13 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.

2.4.3.14 The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.

2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification (refer to 2.3.2) and be supplied by an approved supplier....

2.4.4.8 The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw materials ingredients, packaging materials, and services supplied, and shall contain as a minimum:

- i. Agreed specifications (refer to 2.3.2);
- ii. Reference to the rating of the level of risk applied to a raw material ingredients, packaging materials and services and the approved supplier;
- iii. A summary of the food safety controls implemented by the approved supplier;

- iv. Methods for granting approved supplier status;
- v. Methods and frequency of monitoring approved suppliers;
- vi. Details of the certificates of conformance if required; and
- vii. Methods and frequency of reviewing approved supplier performance and status.

10.7.1.1 The process flow shall be designed to prevent cross contamination and organized so there is a continuous flow of product through the product handling and packaging area.

10.7.2.1 ... Unprocessed field product shall be received and segregated to ensure there is no cross contamination.

93. Despite Fresh Express's assurance that it maintains strict quality control standards from field to delivery, it failed to monitor and require food safety compliance on the part of the grower that supplied the lettuce that caused the *E. coli* outbreak at issue in this case.

94. Despite Fresh Express's assurance that it maintains strict quality control standards from field to delivery, it failed to ensure the raw produce it processed was not contaminated when it arrived at Fresh Express's processing facility, did not become contaminated by comingling and processing with adulterated romaine lettuce, or did not become contaminated by unsanitary conditions at Fresh Express's processing facilities.

95. These long-standing failures, which are contrary to its public representations and assurances, are violations of Fresh Express's food safety obligations and are a direct cause of the illness and damages suffered by the Taylors.

### **iii. Retail Standards**

96. One of the key industry standards for produce safety in retail food establishments, including Safeway, is the "Produce Safety Best Practices Guide for Retailers" published by the food industry association, Food Marketing Institute ("FMI").

1           97.     The January 2014 edition of the “Produce Safety Best Practices Guide for  
2 Retailers” notes that “Prevention of biological, physical and chemical contamination that  
3 can harm consumers should be the focus for all commodities and for all food safety  
4 programs at all stages of the supply chain. Risk factors should be assessed by commodity,  
5 production practices, outbreak history, growing location, intended use and for ready-to-  
6 eat produce.”

7  
8           98.     FMI’s Best Practices outline other practices and procedures that retail  
9 establishments should follow for produce safety, including:

- 10           a.     Assuring that all entities in the chain of distribution – from farm to fork –  
11                 have written food safety programs in place;
- 12           b.     Establishing and communicating produce commodity specifications  
13                 including food safety requirements;
- 14           c.     Working with supply chain partners using a step-based program for all  
15                 farms, including small farms, in which training materials are available to  
16                 strengthen food safety programs;
- 17           d.     Using best practices guidelines for a retailer supplier approval list;
- 18           e.     Verifying that an existing or potential supplier has a food safety  
19                 foundation in place;
- 20           f.     Applying best practices to international and domestic grower/shippers,  
21                 harvesters, coolers, packers, packinghouses, wholesalers and distributors;
- 22           g.     Communicating education and training resources for on-farm produce  
23                 safety;
- 24           h.     Partnering with small growers to help them get started on building their  
25                 food safety plans through outreach, education, and guiding suppliers to  
26                 resources they can use;
- 27           i.     Using cooperative extension services to help with the development and  
28                 maintenance of a food safety foundation;
- j.     Highlighting additional food safety resources for smaller growers in order  
               to ensure that the same food safety foundation is applied to all produce;



- k. Communicating with suppliers on at least an annual basis to address roles, responsibilities and expectations;
- l. Communicating with suppliers to ensure all requirements and specifications are clearly and fairly described and followed;
- m. Using third party audits to verify food safety compliance;
- n. Using volunteer audits administered by the USDA that focuses on best agricultural practices to verify that vegetables including romaine lettuce are produced, packed, handled, and stored in the safest manner possible to minimize the risk of microbial contamination; and
- o. Using self-audits to establish compliance with FDA's 1998 GAP's Guidance, National GAP's Program, or any of the recognized commodity specific food safety guidance.

99. Safeway's website contains links that lead to a "Food Safety" page on Albertson Companies' website, which states as follows:

We're proud to sell safe, high-quality products for you and your family to enjoy worry-free....

Quality assurance is a constant priority for us, from the store level up through our national operations, because it matters to our shoppers. To ensure that we maintain the highest standards of quality, we participate in the Global Food Safety Initiative (GFSI), a collaborative initiative among food safety experts and service providers from retail, manufacturing, food service and supply chain sectors. The GFSI benchmarks existing food standards against food safety criteria and existing practices.

All of Albertsons Companies manufacturing facilities are GFSI-certified, and we are working toward the same certification for the vendor community that manufactures our private-label products — a goal we have almost reached.

100. One GFSI recognized standard is SQF Food Safety Code for Food Retail, Edition 8, the code edition in effect at the time of the outbreak at issue.

101. The SQF retail code has specific provisions for supplier approval, including the following:

2.3.4.4 The approved supplier program shall be based on the prior performance of a supplier and the risk level of the pre-packaged foods, raw materials ingredients, packaging materials, and services supplied, and shall contain as a minimum:

- i. Agreed specifications;
- ii. Reference to the rating of the level of risk applied to products, raw material ingredients, packaging materials and services and the approved supplier;
- iii. A summary of the food safety controls implemented by the approved supplier;
- iv. Methods for granting approved supplier status (including regulation, recall and specification);
- v. Methods and frequency of monitoring approved suppliers;
- vi. Details of the certificates of conformance if required, and
- vii. Methods and frequency of reviewing approved supplier performance and status.

2.3.4.5 A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained....

2.4.1.2 The organization shall ensure that, at the time of sale to its customer and/or consumer, the food sold shall comply with the legislation that applies to the food and its production in the country of its origin and destination. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, nutritional, allergen and additive labeling, and to relevant established industry codes of practice.

102. Safeway made no meaningful effort to monitor or require food safety compliance on the part of the suppliers of food products it sold in its stores, including Fresh Express and the supplier of the adulterated romaine lettuce incorporated into the salad product at issue.

103. These long-standing failures, which are absolutely contrary to its public representations and assurances, are violations of Safeway's food safety obligations and are a direct cause of the illness and damages suffered by the Taylors.

**C. Prior Outbreaks Associated with Produce**

104. Despite guidance and regulations intended to prevent *E. coli* O157:H7 and other pathogenic outbreaks associated with lettuce and other leafy greens, these outbreaks have been repeatedly recurring over the last 25 years.

105. Outlined below is a list of *E. coli* outbreaks involving contaminated lettuce or leafy greens:

| Date               | Vehicle                             | Etiology                                   | Confirmed Cases | States/Provinces      |
|--------------------|-------------------------------------|--------------------------------------------|-----------------|-----------------------|
| July 1995          | Lettuce (leafy green; red; romaine) | <i>E. coli</i> O157:H7                     | 74              | 1:MT                  |
| Sept. 1995         | Lettuce (romaine)                   | <i>E. coli</i> O157:H7                     | 20              | 1:ID                  |
| Sept. 1995         | Lettuce (iceberg)                   | <i>E. coli</i> O157:H7                     | 30              | 1:ME                  |
| Oct. 1995          | Lettuce (iceberg; unconfirmed)      | <i>E. coli</i> O157:H7                     | 11              | 1:OH                  |
| May-June 1996      | Lettuce (mesclun; red leaf)         | <i>E. coli</i> O157:H7                     | 61              | 3:CT, IL, NY          |
| May 1998           | Salad                               | <i>E. coli</i> O157:H7                     | 2               | 1:CA                  |
| Feb.-Mar. 1999     | Lettuce (iceberg)                   | <i>E. coli</i> O157:H7                     | 72              | 1:NE                  |
| Oct. 1999          | Salad                               | <i>E. coli</i> O157:H7                     | 92              | 3:OR, PA, OH          |
| Oct. 2000          | Lettuce                             | <i>E. coli</i> O157:H7                     | 6               | 1:IN                  |
| Nov. 2001          | Lettuce                             | <i>E. coli</i> O157:H7                     | 20              | 1:TX                  |
| July-Aug. 2002     | Lettuce (romaine)                   | <i>E. coli</i> O157:H7                     | 29              | 2:WA, ID              |
| Nov. 2002          | Lettuce                             | <i>E. coli</i> O157:H7                     | 13              | 1:IL                  |
| Dec. 2002          | Lettuce                             | <i>E. coli</i> O157:H7                     | 3               | 1:MN                  |
| Oct. 2003-May 2004 | Lettuce (mixed salad)               | <i>E. coli</i> O157:H7                     | 57              | 1:CA                  |
| Apr. 2004          | Spinach                             | <i>E. coli</i> O157:H7                     | 16              | 1:CA                  |
| Nov. 2004          | Lettuce                             | <i>E. coli</i> O157:H7                     | 6               | 1:NJ                  |
| Sept. 2005         | Lettuce (romaine)                   | <i>E. coli</i> O157:H7                     | 32              | 3:MN, WI, OR          |
| Sept. 2006         | Spinach (baby)                      | <i>E. coli</i> O157:H7 and other serotypes | 205             | Multistate and Canada |
| Nov./Dec. 2006     | Lettuce                             | <i>E. coli</i> O157:H7                     | 71              | 4:NY, NJ, PA, DE      |
| Nov./Dec. 2006     | Lettuce                             | <i>E. coli</i> O157:H7                     | 81              | 3:IA, MN, WI          |
| July 2007          | Lettuce                             | <i>E. coli</i> O157:H7                     | 26              | 1:AL                  |
| May 2008           | Romaine                             | <i>E. coli</i> O157:H7                     | 9               | 1:WA                  |
| Oct. 2008          | Lettuce                             | <i>E. coli</i> O157:H7                     | 59              | Multistate and Canada |
| Nov. 2008          | Lettuce                             | <i>E. coli</i> O157:H7                     | 130             | Canada                |

|              |                                    |                        |     |                          |
|--------------|------------------------------------|------------------------|-----|--------------------------|
| Sept. 2009   | Lettuce:<br>Romaine or<br>Iceberg  | <i>E. coli</i> O157:H7 | 29  | Multistate               |
| Sept. 2009   | Lettuce                            | <i>E. coli</i> O157:H7 | 10  | Multistate               |
| April 2010   | Romaine                            | <i>E. coli</i> O145    | 33  | 5:MI, NY, OH,<br>PA, TN  |
| Oct. 2011    | Romaine                            | <i>E. coli</i> O157:H7 | 60  | Multistate               |
| April 2012   | Romaine                            | <i>E. coli</i> O157:H7 | 28  | 1:CA<br><br>Canada       |
| June 2012    | Romaine                            | <i>E. coli</i> O157:H7 | 52  | Multistate               |
| Sept. 2012   | Romaine                            | <i>E. coli</i> O157:H7 | 9   | 1:PA                     |
| Oct. 2012    | Spinach and<br>Spring Mix<br>Blend | <i>E. coli</i> O157:H7 | 33  | Multistate               |
| Apr. 2013    | Leafy Greens                       | <i>E. coli</i> O157:H7 | 14  | Multistate               |
| Aug. 2013    | Leafy Greens                       | <i>E. coli</i> O157:H7 | 15  | 1:PA                     |
| Oct. 2013    | Ready-To-Eat<br>Salads             | <i>E. coli</i> O157:H7 | 33  | Multistate               |
| Apr. 2014    | Romaine                            | <i>E. coli</i> O126    | 4   | 1:MN                     |
| Apr. 2015    | Leafy Greens                       | <i>E. coli</i> O145    | 7   | 3:MD, SC, VA             |
| June 2016    | Mesclun Mix                        | <i>E. coli</i> O157:H7 | 11  | 3:IL, MI, WI             |
| Nov. 2017    | Leafy Greens                       | <i>E. coli</i> O157:H7 | 67  | Multistate and<br>Canada |
| March 2018   | Romaine                            | <i>E. coli</i> O157:H7 | 201 | Multistate and<br>Canada |
| October 2018 | Romaine                            | <i>E. coli</i> O157:H7 | 62  | Multistate and<br>Canada |

**D. Outbreaks in the fall of 2016, 2017, and 2018**

106. The multistate *E. coli* outbreak associated with romaine lettuce that occurred in the fall of 2018, referenced above, was investigated by the FDA, CDC, and other public health entities.

107. On February 13, 2019, the FDA published its “Investigation Summary: Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Fall 2018 Multi-State Outbreak of *E. Coli* O157:H7.”

108. This Investigation Summary noted that “All *E. coli* O157:H7 isolates from ill consumers had a rare genetic fingerprint, as determined by whole genome sequencing, that was

1 closely related to one previously seen in ill consumers in the U.S. and Canada in the Fall of 2016  
2 and the Fall of 2017.”

3 109. Assisted by historical, epidemiological, and traceback analyses from the 2016 and  
4 2017 outbreaks, as well as new information, government traceback investigations narrowed the  
5 geographic origin of contaminated romaine lettuce in the fall of 2018 outbreak to three counties  
6 in California.  
7

8 110. The FDA’s Investigation Summary observes that the outbreak strain was collected  
9 from sediment of an on-farm water reservoir used by one of the farms implicated in the fall of  
10 2018 outbreak.

11 111. The FDA’s Investigation Summary concluded that this on-farm water reservoir  
12 was not effectively treated with sanitizer to ensure that water used to contact romaine lettuce at  
13 harvest, during postharvest handling, and to wash and rinse harvest equipment food contact  
14 surfaces was not contaminated with pathogenic bacteria.  
15

16 112. The FDA’s Investigation Summary concluded that, while it was uncertain how the  
17 outbreak strain of *E. coli* O157:H7 was introduced into this on-farm reservoir:

18 evidence of extensive wild animal activity, including waterfowl, rodents, coyotes,  
19 etc., and animal burrows near the contaminated reservoir sediment was noted by  
20 the investigation team and likely warrants consideration as a possible source(s) of  
21 the human pathogen found in the on-farm water reservoir. Additionally, adjacent  
22 land use including the use of soil amendments, or for animal grazing on nearby  
land by cattle and horses, may have had the potential to be reservoirs of *E. coli*  
O157:H7.

23 113. The FDA’s Investigation Summary further concluded that “Foodborne illness  
24 outbreaks caused by this specific strain of *E. coli* O157:H7 occurred in 2016, 2017, and 2018,  
25 indicating that the outbreak strain may have either persisted in the environment or may been  
26 repeatedly introduced into the environment from an unknown source.”  
27  
28

114. The FDA’s February 13, 2019, Investigative Summary further observed that, “industry has the responsibility for ensuring that the foods they bring to market are safe for consumers to eat. All segments of the leafy greens industry should thoroughly review current operations, procedures, policies and practices taking into consideration the findings of this investigation report, the [FDA Food Safety Modernization Act (“FSMA”)] Product Safety Rule, the FSMA Preventive Controls for Human Foods Rule and other relevant FSMA regulations.”

115. The Investigation Summary recommended that entities in the leafy green industry assess their operations for compliance with applicable requirements of the FSMA Produce Safety Rule and GAPs, including:

- a. Assure all agricultural water used by growers is safe and of adequate sanitary quality, which may include:
  - i. Develop and use of water treatment protocols, including treatment verification;
  - ii. Assess and mitigate risks related to wild animal intrusion;
  - iii. Assess and mitigate risks related to land uses near or adjacent to agricultural water sources that may contaminate agricultural water;
- b. Perform a root cause analysis (“RCA”) to determine the likely source of the contamination, if prevention measures have failed, and whether additional measures are needed to prevent reoccurrence;
- c. Conduct routine pre-harvest and finished product verification testing; and
- d. Be able to trace product back to the specific source in real time.

116. The Investigation Summary states that “The FDA recommendations as a result of this investigation are similar to and reinforce the changes recommended in the Environmental Assessment associated with the Spring of 2018 STEC outbreak associated with romaine lettuce from the Yuma growing region.” Those recommendations included assessment of water safety, assessment and mitigation of risks related to nearby land uses (including CAFO operations),

1 verify suppliers' consistent implementation of food safety procedures, policies, and practices,  
2 and root cause analyses ("RCA") to determine the cause of prior adulteration events.

3 117. Defendants failed to implement these recommendations.

4 118. A RCA is a method of assessing problems based on their root causes. It analyzes  
5 the underlying factors in any given adverse reaction to identify a problem's source and corrective  
6 measures to fix it. This process delves deeper than FDA outbreak investigations to find answers  
7 based on hidden causes and their effects, rather than merely looking at the most apparent.  
8

9 119. Despite RCA's long and successful application in assessing and preventing unsafe  
10 practices, both of the Defendants failed to perform and document a RFA to identify the root  
11 cause of the repeated leafy green adulteration outbreaks and the role that contaminated  
12 agricultural water played in causing them.  
13

14 120. Had such a RCA been conducted in the years prior to this outbreak, the data  
15 obtained therefrom would have allowed each of the Defendants to prevent the use of  
16 contaminated irrigation water that caused this outbreak.

17 121. Despite the 2016, 2017, and 2018 *E. coli* O157:H7 outbreaks, and warnings from  
18 the CDC, FDA, state and local health officials, scholars, trade groups, and others, STEC  
19 outbreaks continued to occur.

20 122. Despite repeated and deadly STEC outbreaks over the course of more than a  
21 decade, and means by which to prevent them, outbreaks continued to occur because growers,  
22 harvesters, distributors, processors, retailers, and other entities in the supply chain, including the  
23 Defendants, failed to implement and follow—or require their suppliers to implement and  
24 follow—safe practices that would have prevented the risk of the ongoing outbreaks including the  
25 one at issue in this case.  
26  
27  
28

123. Despite the long history of outbreaks associated with leafy greens, including romaine lettuce, the leafy green industry, including the Defendants, resisted efforts to impose certain mandatory safety standards.

**E. Romaine Lettuce Linked to the Fall of 2019 *E. coli* O157:H7 Outbreak**

124. Given the number of *E. coli* outbreaks associated with salad product and produce over the last two decades, and warnings from the CDC, FDA, state and local health officials, scholars, trade groups, and others, the risk of another *E. coli* outbreak was known and/or reasonably foreseeable to ordinarily prudent growers, harvesters, distributors, processors, manufacturers, and sellers of romaine lettuce, including the Defendants, prior to October 31, 2019.

125. Given the foreseeable risk of another *E. coli* outbreak associated with salad product and produce prior to October 31, 2019, growers, processors, distributors, manufacturers, and sellers of romaine lettuce had a duty, among other things, to:

- a. Identify potential sources of *E. coli* contamination;
- b. Eliminate, or guard against, sources of potential *E. coli* contamination, including but not limited by:
  - i. Maintaining safe and sanitary conditions at their facilities;
  - ii. Using safe and sanitary irrigation, washing, and chemical treatment methods;
  - iii. Choosing suppliers that utilized safe and sanitary procedures; and
  - iv. Sterilizing any *E. coli* bacteria that had contaminated harvested romaine lettuce; and
- c. Warn consumers of romaine lettuce regarding the risk of *E. coli* contamination.

126. Each of the Defendants failed to fulfill the duties listed in the preceding paragraph.

127. Entities in the food distribution chain, including the Defendants, failed to require,



1 implement, follow, and/or document compliance with accepted practices, government and  
2 industry guidance documents, GAPs, GMPs, and peer reviewed scientific journals, among other  
3 things, that enunciate the standard of care regarding safe use and application of water to green  
4 leafy vegetables, including romaine lettuce.

5  
6 128. Prior to the fall of 2019 outbreak, the entities in the supply chain, including the  
7 Defendants, failed to conduct appropriate assessments, testing, verification, and RCAs to ensure  
8 salad product adulterated with dangerous *E. coli* O157:H7 was not sold to and consumed by the  
9 public.

10 129. The Defendants' failure to fulfill these duties caused the fall of 2019  
11 outbreak that resulted in the illnesses, injuries, and damages of A.T., K.T., T.T., and B.T.

12  
13 130. In November of 2019, the FDA, the CDC, and state health authorities announced  
14 they were investigating an outbreak of illnesses caused by *E. coli* O157:H7 associated with  
15 romaine lettuce, which consisted of three concurrent outbreaks: one that included cases in the  
16 United States and Canada; one that Washington state potentially linked to leafy greens; and a  
17 third outbreak, with cases in the United States and Canada, linked to Fresh Express Sunflower  
18 Crisp Chopped Salad Kits (collectively "fall of 2019 outbreak").

19 131. The investigation of the fall of 2019 outbreak was announced just as another *E.*  
20 *coli* O157:H7 outbreak had ended. Specifically, on October 31, 2019, the FDA announced it had  
21 been investigating an *E. coli* O157:H7 outbreak involving 23 illnesses that was likely associated  
22 with romaine lettuce. At the time of the FDA's announcement, the active investigation had ended  
23 and the outbreak appeared to be over.

24  
25 132. The fall of 2019 outbreak was even more severe. Illness related to the outbreak  
26 strain of *E. coli* O157:H7 appeared on September 20, 2019, and were observed until December  
27 21, 2019. The illness affected a wide range of individuals from the ages of less than 1 to 89 years  
28

old. Of the 167 people with information available, 85 (52%) required hospitalization, and 14 of those individuals developed HUS.

133. Epidemiological, laboratory, and traceback evidence indicated that romaine lettuce from the Salinas, California growing region was a likely source of this outbreak.

134. Traceback analyses on the outbreak identified a common grower in Salinas, though the identity of that grower has not been released.

135. In December of 2019, testing by the Wisconsin Department of Health Services detected *E. coli* in an unopened bag of Fresh Express brand Leafy Green Romaine. The source identified on the bag was Salinas, California.

136. The 2019 outbreak at issue also occurred because Defendants Safeway and Fresh Express failed to follow the preventive control strategies outlined by the FDA, the CA- and AZ-LGMA, industry groups, academicians and scientists, and others, including those described above.

137. Defendants failed to remove adulterated salad product from the market, which increased the severity and impact of the 2019 outbreak.

138. Defendants made no meaningful effort to recall products containing adulterated romaine or otherwise warn consumers about the risk of serious harm from adulterated romaine lettuce sold by Defendants.

#### **F. The Taylors' Infection by *E. coli* O157:H7**

##### **i. *Defendants Sold Tainted Salad Product to the Taylors***

139. Prior to October 31, 2019, the health and development of the four Taylor children were normal.

140. On October 31, 2019, the Taylors purchased two bags of Fresh Express American salad from the Safeway store located at 2901 F. Road in Grand Junction, Colorado, as reflected on the following receipt as “2 QTY FE AMRCN S”:

| PRODUCE              |        |   |
|----------------------|--------|---|
| PARTY PCK DIP TRAY   | 12.00  | S |
| GRAPES MIXED         | 4.99   | B |
| STRAWBERRY BOWL      | 4.99   | B |
| PREMIUM VEGETABLE    | 12.99  | B |
| MELON MEDLEY         | 7.99   | B |
| MELON MEDLEY         | 7.99   | B |
| 2.78 lb @ \$0.59 /lb |        |   |
| WT BANANAS YELLOW    | 1.64   | S |
| 2 QTY FE AMRCN S     | 5.38   | S |
| Regular Price        | 5.98   |   |
| Sale Savings         | 0.60-  |   |
| LITEHOUSE HS RANCH   | 5.99   | S |
| 2.98 lb @ \$2.99 /lb |        |   |
| WT HONEYCRISP APPLES | 8.91   | S |
| TAX                  | 4.67   |   |
| **** BALANCE         | 255.88 |   |

141. The produce in this salad mix was grown, processed, manufactured, marketed, and/or sold by Fresh Express.

142. The Fresh Express American salad kit at issue contained romaine lettuce, as demonstrated by the product packaging:



143. The romaine lettuce in the Fresh Express American salad purchased and consumed by members of the Taylor family was contaminated with the same strain of *E. coli* O157:H7 implicated in the above-described multistate outbreak.

ii. *A.T.'s Illness*

144. Between October 31, 2019, and November 4, 2019, eight-year-old A.T. consumed Defendants' adulterated salad product.

145. On or about November 4, 2019, A.T. began experiencing the onset of *E. coli* symptoms which included abdominal pain, fatigue, vomiting, and diarrhea.

146. Subsequently A.T.'s symptoms continued and intensified. She also developed the hallmark symptom of an STEC infection: profuse bloody diarrhea.

147. Over the course of the next few days, A.T. remained in a constant state of distress, suffering from the same painful symptoms.

148. A.T. was brought to the emergency room where lab work was done, including a stool sample.

149. A.T.'s stool sample tested positive for Shiga toxin producing *E. Coli*.

150. A.T.'s stool culture proved to be genetically related to the outbreak strains of *E. coli* O157:H7 associated with romaine lettuce produced in the Salinas Valley of California.

151. The only adulterated food consumed by A.T. during the incubation period for *E. coli* O157:H7 was the salad product sold by Defendants Fresh Express and Safeway to the Taylors on October 31, 2019.

152. On or about November 7, 2019, A.T. was admitted to St. Mary's Hospital. By this time, her diarrhea was "grossly bloody."

153. A.T. was diagnosed with HUS and acute renal failure.

154. A.T.'s condition deteriorated and she was transferred to the Children's Hospital on November 9, 2019, for further care of her *E. coli* infection.

155. A.T.'s condition continued to deteriorate, as her HUS became complicated by central nervous system involvement with encephalopathy.

1 156. A.T. remains hospitalized at Children's Hospital.

2 157. A.T.'s condition has required invasive and painful medical treatment.

3 158. A.T.'s injuries are permanent.

4 159. A.T. is at risk in the future for development of further kidney, cardiovascular, and  
5 neurological complications from her injuries.

6  
7 160. A.T. contracted her confirmed *E. coli* O157:H7 illness by consuming the  
8 Defendants' *E. coli* O157:H7-contaminated salad product.

9 161. A.T. suffered injury and damages as a direct and proximate result of the defective  
10 and unreasonably dangerous condition of the adulterated salad product that Defendants grew,  
11 processed, manufactured, distributed, marketed, and/or sold. A.T. has suffered and will continue  
12 to suffer significant injuries and damages including but not limited to: past and future physical  
13 and emotional injury, past and future medical costs and expenses, past and future physical and  
14 mental pain and suffering, past and future discomfort and loss of enjoyment of life, past and  
15 future wage loss, loss of earning capacity, and other damages to be proved at trial.

16  
17 **iii. K.T.'s Injuries**

18 162. Between October 31, 2019, and November 6, 2019, ten-year-old K.T. consumed  
19 Defendants' adulterated salad product.

20 163. On or about November 6, 2019, K.T. began experiencing the onset of *E. coli*  
21 symptoms that included abdominal pain, fatigue, vomiting and diarrhea.

22 164. Subsequently K.T.'s symptoms continued and intensified. He also developed the  
23 hallmark symptom of an STEC infection: profuse bloody diarrhea.

24 165. Over the course of the next few days, K.T. remained in a constant state of distress,  
25 suffering from the same painful symptoms.

26  
27 166. On or about November 7, 2019, K.T. was admitted to St. Mary's Hospital along  
28

1 with his sister, A.T.

2 167. While at St. Mary's Hospital, a stool sample taken from K.T., which tested  
3 positive for Shiga toxin producing *E. coli*.

4 168. K.T.'s stool culture proved to be genetically related to the outbreak strains of *E.*  
5 *coli* O157:H7 associated with romaine lettuce produced in the Salinas Valley of California.

6 169. The only adulterated food consumed by K.T. during the incubation period for *E.*  
7 *coli* O157:H7 was the salad product sold by Defendants Fresh Express and Safeway to the  
8 Taylors on October 31, 2019.

9 170. K.T. remained at St. Mary's Pediatric for several more days, but his conditioned  
10 deteriorated and he was transferred to the Children's Hospital on November 9, 2019, for further  
11 care of his *E. coli* infection.

12 171. K.T. was diagnosed with HUS.

13 172. K.T. remained hospitalized at Children's Hospital until November 17, 2019.

14 173. During this prolonged hospitalization, K.T. experienced continued physical  
15 problems, including but not limited to acute kidney injury and anemia.

16 174. K.T.'s condition has required invasive and painful medical treatment.

17 175. K.T.'s injuries are permanent.

18 176. K.T. is at risk in the future for development of further kidney and cardiovascular  
19 complications from his injuries.

20 177. K.T. contracted his confirmed *E. coli* O157:H7 illness by consuming the  
21 Defendants' *E. coli* O157:H7-contaminated salad product.

22 178. K.T. suffered injury and damages as a direct and proximate result of the defective  
23 and unreasonably dangerous condition of the adulterated salad product that Defendants grew,  
24 processed, manufactured, distributed, marketed, and/or sold. K.T. has suffered and will continue  
25  
26  
27  
28

1 to suffer significant injuries and damages including but not limited to: past and future physical  
 2 and emotional injury, past and future medical costs and expenses, past and future physical and  
 3 mental pain and suffering, past and future discomfort and loss of enjoyment of life, past and  
 4 future wage loss, loss of earning capacity, and other damages to be proved at trial.

5 **iii. T.T.'s Injuries**

6  
 7 179. Between October 31, 2019, and November 8, 2019, nine-month-old T.T. was  
 8 exposed to other members of the Taylor family who were infected with *E. coli* O157:H7 as a  
 9 result of their consumption of Defendants' adulterated salad products.

10 180. On or about November 8, 2019, T.T. began experiencing the onset of *E. coli*  
 11 symptoms which included diarrhea and dehydration.

12 181. On or about November 11, 2019, T.T. presented to his primary care physician for  
 13 treatment of diarrhea and decreased intake.

14 182. A stool sample was taken from T.T. on November 11, 2019.

15 183. T.T.'s stool sample tested positive for Shiga toxin producing *E. coli*.

16 184. T.T.'s stool culture proved to be genetically related to the outbreak strains of *E.*  
 17 *coli* O157:H7 associated with romaine lettuce produced in the Salinas Valley of California.

18 185. T.T. did not consume any adulterated food during the incubation period for *E. coli*  
 19 O157:H7, but was secondarily exposed to the outbreak strain of *E. coli* that contaminated the  
 20 salad product at issue, which caused his confirmed *E. coli* O157:H7 illness.

21 186. On or about November 13, 2019, T.T. was admitted to Children's Hospital, where  
 22 two of his siblings had been already admitted. T.T. remained there until November 16, 2019.

23 187. During this hospitalization, T.T. experienced continued physical problems,  
 24 including but not limited to viral croup, continued dehydration, and diarrhea.

25 188. T.T. suffered injury and damages as a direct and proximate result of the defective  
 26  
 27  
 28

1 and unreasonably dangerous condition of the adulterated salad product that Defendants grew,  
 2 processed, manufactured, distributed, marketed, and/or sold. T.T. has suffered and will continue  
 3 to suffer significant injuries and damages including but not limited to: past and future physical  
 4 and emotional injury, past and future medical costs and expenses, past and future physical and  
 5 mental pain and suffering, past and future discomfort and loss of enjoyment of life, past and  
 6 future wage loss, loss of earning capacity, and other damages to be proved at trial.

8 **iv. B.T.'s Injuries**

9 189. Between October 31, 2019, and November 15, 2019, four-year-old B.T. was  
 10 exposed to other members of the Taylor family who were infected with *E. coli* O157:H7 as a  
 11 result of their consumption of Defendants' adulterated salad products.

12 190. On or about November 15, 2019, B.T. began experiencing the onset of *E. coli*  
 13 symptoms which included abdominal pain, fatigue, diarrhea, and dehydration.

14 191. B.T. also developed the hallmark symptom of an STEC infection: profuse bloody  
 15 diarrhea.

16 192. On or about November 16, 2019, B.T. was admitted to Children's Hospital where  
 17 all of his siblings had been admitted.

18 193. While B.T. was at Children's Hospital, a stool sample was taken, which tested  
 19 positive for Shiga toxin producing *E. coli*.

20 194. B.T.'s stool culture proved to be genetically related to the outbreak strains of *E.*  
 21 *coli* O157:H7 associated with romaine lettuce produced in the Salinas Valley of California.

22 195. B.T. did not consume any adulterated food during the incubation period for *E. coli*  
 23 O157:H7, but was secondarily exposed to the outbreak strain of *E. coli* that contaminated the  
 24 salad product at issue, which caused his confirmed *E. coli* O157:H7 illness.

25 196. B.T. was diagnosed with HUS, acute kidney injury, anemia, and  
 26  
 27  
 28



1 thrombocytopenia.

2 197. B.T. remained hospitalized from November 16, 2019 until November 29, 2019.

3 198. B.T.'s condition has required invasive and painful medical treatment.

4 199. B.T.'s injuries are permanent.

5 200. B.T. is at risk in the future for development of further kidney, cardiovascular, and  
6  
7 neurological complications from his injuries.

8 201. B.T. suffered injury and damages as a direct and proximate result of the defective  
9 and unreasonably dangerous condition of the adulterated salad product that Defendants grew,  
10 processed, manufactured, distributed, marketed, and/or sold. B.T. has suffered and will continue  
11 to suffer significant injuries and damages including but not limited to: past and future physical  
12 and emotional injury, past and future medical costs and expenses, past and future physical and  
13 mental pain and suffering, past and future discomfort and loss of enjoyment of life, past and  
14 future wage loss, loss of earning capacity, and other damages to be proved at trial.

15  
16 **v. *Eric Taylor and Kayla Taylor***

17 202. As a direct and proximate result of Defendants' conduct, and A.T., K.T., T.T., and  
18 B.T.'s resulting illnesses, Eric Taylor and Kayla Taylor have incurred medical and other  
19 expenses arising from the treatment of their minor children.

20 203. As a direct and proximate result of Defendants' conduct, and A.T., K.T., T.T., and  
21 B.T.'s resulting illnesses, Eric Taylor and Kayla Taylor have missed significant amounts of time  
22 from work, and have sustained and will continue to sustain wage loss because of their minor  
23 children's injuries.

24 204. As a direct and proximate result of Defendants' conduct, and A.T.'s resulting  
25 illnesses, Eric Taylor and Kayla Taylor have lost the love, care, affection, companionship, and  
26 other pleasures of the family relationship with their daughter, A.T.  
27  
28

205. As a proximate or direct cause of Defendants' conduct, Eric Taylor and Kayla Taylor have suffered irreparable emotional distress.

**First Claim for Relief**

(Strict Liability of Fresh Express: Manufacturing Defect)

206. The Taylors incorporate the allegations in the preceding paragraphs as if fully set forth herein.

207. Fresh Express grew, harvested, processed, manufactured, distributed, and/or sold the adulterated salad product that caused the Taylors' injuries.

208. Fresh Express is in the business of growing, harvesting, processing, manufacturing, distributing, marketing, and/or selling salad products.

209. Growers and harvesters that supplied romaine lettuce to Fresh Express were Fresh Express's actual agents. Therefore, Fresh Express is liable for the acts and omissions of those growers and harvesters that supplied the adulterated romaine lettuce that caused the Taylors' damages.

210. Growers and harvesters that supplied romaine lettuce to Fresh Express were Fresh Express's ostensible agents. Therefore, Fresh Express is liable for the acts and omissions of those growers and harvesters that supplied the adulterated romaine lettuce that caused the Taylors' damages.

211. Fresh Express had a duty to grow, harvest, process, manufacture, distribute, and sell salad products that were reasonably safe, wholesome, free of defects, and that otherwise complied with applicable federal, state, and local laws, ordinances, and regulations, and that were clean, free from adulteration, and safe for human consumption.

212. Salad products and other produce that are contaminated with *E. coli* O157:H7 are unfit, unsuitable, and unreasonably dangerous for their intended and ordinary and expected

1 purpose of human consumption because *E. coli* O157:H7 is a bacterium dangerous to human  
2 health.

3         213. The adulterated salad product that Fresh Express grew, harvested, rocessed,  
4 manufactured, distributed, marketed, and sold to and consumed by the Taylors was, at the time it  
5 left Fresh Express's control, defective and unreasonably dangerous for its intended and ordinary  
6 and expected purpose because it was contaminated with *E. coli* O157:H7.

7  
8         214. Because the adulterated salad product was contaminated with *E. coli* O157:H7, it  
9 was in a condition that consumers—including the Taylors—had not contemplated, and it was in  
10 a condition that rendered it unreasonably dangerous for its intended and ordinary and expected  
11 purpose.

12         215. The Taylors were reasonably foreseeable and intended users of Fresh Express's  
13 defective salad product.

14         216. The contaminated lettuce also did not contain warnings or instructions indicating  
15 that the product was unreasonably dangerous due to the contamination.

16  
17         217. The salad product contaminated with *E. coli* O157:H7 reached the Taylors  
18 without substantial change in the condition in which it was sold by Fresh Express. The Taylors  
19 used the product in the manner expected and intended, including when they consumed it.

20         218. An ordinarily prudent grower, harvester, processor, manufacturer, distributor,  
21 and/or seller of salad products containing romaine lettuce and other produce, being fully aware  
22 of the risks of *E. coli* O157:H7 adulteration, would not place a contaminated salad product on the  
23 market.

24  
25         219. Fresh Express grew, harvested, processed, manufactured, distributed, marketed,  
26 and/or sold the salad product that was consumed by members of the Taylor family.



1           228. The adulterated salad product that Safeway distributed, marketed, and sold to and  
2 consumed by the Taylors was, at the time it left Safeway's control, defective and unreasonably  
3 dangerous for its intended and ordinary and expected purpose because it was contaminated with  
4 *E. coli* O157:H7.

5           229. Because the adulterated salad product was contaminated with *E. coli* O157:H7, it  
6 was in a condition that consumers—including the Taylors—had not contemplated, and it was in  
7 a condition that rendered it unreasonably dangerous for its intended and ordinary and expected  
8 purpose.

9           230. The contaminated lettuce also did not contain warnings or instructions indicating  
10 that the product was unreasonably dangerous due to the contamination.

11           231. The salad product contaminated with *E. coli* O157:H7 reached the Taylors  
12 without substantial change in the condition in which it was sold by Safeway. The Taylors used  
13 the product in the manner expected and intended, including when they consumed it.

14           232. An ordinarily prudent distributor, marketer, and seller of salad products  
15 containing romaine lettuce and other produce, being fully aware of the risks of *E. coli* O157:H7  
16 adulteration, would not sell a contaminated salad product to consumers.

17           233. The Taylors were reasonably foreseeable and intended users of Safeway's  
18 defective salad product.

19           234. Safeway distributed, marketed, and sold the romaine lettuce that was consumed  
20 by members of the Taylor family.

21           235. The contaminated salad product Safeway distributed, marketed, and sold directly  
22 and proximately caused A.T., K.T., T.T., and B.T.'s infection and injuries.

1           236. The Taylors suffered damages as a direct and proximate result of the defective  
2 and unreasonably dangerous condition of the adulterated food product that the Safeway  
3 distributed, marketed, and sold, in an amount to be proven at trial.

4           237. Safeway is therefore strictly liable to the Taylors for all injuries and damages  
5 proximately caused by the exposure to the product.

6  
7                           **Third Claim for Relief**  
8                           (Strict Liability of Fresh Express: Failure to Warn)

9           238. The Taylors incorporate the allegations in the preceding paragraphs as if fully set  
10 forth herein.

11           239. The adulterated food product that Fresh Express grew, harvested, processed,  
12 manufactured, distributed, and sold, and that was consumed by Taylors, was defective and  
13 unreasonably dangerous at the time it left Fresh Express's control.

14           240. Fresh Express had a duty to provide adequate warnings regarding dangers  
15 associated with the use or consumption of its products.

16           241. It was reasonably foreseeable to Fresh Express that the consumption of  
17 adulterated salad product at issue posed a substantial danger to the public, and this danger was  
18 not readily recognized by an ordinary user such as the Taylors.

19           242. Fresh Express knew, or should have known, that that the adulterated salad product  
20 at issue did not provide adequate warnings of the danger associated with *E. coli* contamination  
21 and did not contain proper instructions for reasonably safe human consumption.

22           243. The Taylors suffered injury and damages as a direct and proximate result of Fresh  
23 Express's failure to warn in an amount to be proven at trial.

24           244. Fresh Express is therefore liable to the Taylors for all injuries and damages  
25 proximately caused by the exposure to the defective and unsafe products under California and  
26 other applicable law.  
27  
28

**Fourth Claim for Relief**

(Strict Liability of Safeway: Failure to Warn)

245. The Taylors incorporate the allegations in the preceding paragraphs as if fully set forth herein.

246. The adulterated food product that Safeway distributed, marketed, and sold, and that was consumed by Taylors, was defective and unreasonably dangerous at the time it left Safeway's control.

247. Safeway had a duty to provide adequate warnings regarding dangers associated with the use or consumption of its products.

248. It was reasonably foreseeable to Safeway that the consumption of adulterated salad product at issue posed a substantial danger to the public, and this danger was not readily recognized by an ordinary user such as the Taylors.

249. Safeway knew, or should have known, that that the adulterated salad product at issue did not provide adequate warnings of the danger associated with *E. coli* contamination and did not contain proper instructions for reasonably safe human consumption.

250. The Taylors suffered injury and damages as a direct and proximate result of the Safeway's failure to warn in an amount to be proven at trial.

251. Safeway is therefore liable to the Taylors for all injuries and damages proximately caused by the exposure to the defective and unsafe products under California and other applicable law.

**Fifth Claim for Relief**

(Breach of Implied Warranty: Fresh Express)

252. The Taylors incorporate the allegations in the preceding paragraphs as if fully set forth herein.

253. Fresh Express owed a duty to the Taylors to manufacture, distribute, and sell a

1 product that conformed to implied warranties including, but not limited to, the implied warranty  
2 of merchantability and implied warranty of fitness.

3 254. The salad product manufactured, distributed, and sold by Fresh Express was  
4 contaminated with *E. coli* O157:H7 bacteria.

5 255. Fresh Express breached the implied warranty of merchantability because the salad  
6 product it manufactured, distributed, and sold would not pass without objection in the trade, and  
7 was unfit for the ordinary purposes for which such goods were intended and used, *i.e.* human  
8 consumption.

9 256. Fresh Express breached the implied warranty of fitness because it had reason to  
10 know of the particular purpose for which the salad product was required, *i.e.* human  
11 consumption, and that the Taylors and other consumers relied on Fresh Express's skill and  
12 judgment to select and furnish suitable salad product.

13 257. Because Fresh Express manufactured, distributed, and sold food that was in  
14 breach of its implied warranties, Fresh Express is liable to the Taylors for the proximate damages  
15 and harms caused by its contaminated food.

16 258. Proper and timely notice of this claim was given.

17 259. As a direct and proximate result of the breach of warranty, the Taylors sustained  
18 the injuries and damages in an amount to be proven at trial.

19 260. Fresh Express is therefore liable to the Taylors for all damages proximately  
20 caused by Fresh Express's breach of warranty.

21 **Sixth Claim for Relief**

22 (Breach of Implied Warranty: Safeway)

23 261. The Taylors incorporate the preceding paragraphs by this reference as if each  
24 paragraph was set forth herein in its entirety.

25 262. Safeway owed a duty to the Taylors to distribute and sell a product that conformed



1 to implied warranties including, but not limited to, the implied warranty of merchantability and  
2 implied warranty of fitness.

3 263. The salad product distributed and sold by Safeway was contaminated with *E. coli*  
4 O157:H7 bacteria.

5 264. Safeway breached the implied warranty of merchantability because the salad  
6 product it distributed and sold would not pass without objection in the trade, and was unfit for the  
7 ordinary purposes for which such goods were intended and used, *i.e.* human consumption.

8 265. Safeway breached the implied warranty of fitness because it had reason to know of  
9 the particular purpose for which the salad product was required, *i.e.* human consumption, and that  
10 the Taylors and other consumers relied on Safeway's skill and judgment to select and furnish  
11 suitable salad product.

12 266. Because Safeway distributed and sold food that was in breach of its implied  
13 warranties, Safeway is liable to the Taylors for the proximate harms caused by its contaminated  
14 food.

15 267. Proper and timely notice of this claim was given.

16 268. As a direct and proximate result of the breach of warranty, the Taylors sustained  
17 the injuries and damages in an amount to be proven at trial.

18 269. Safeway is therefore liable to the Taylors for all damages proximately caused by  
19 Safeway's breach of warranty.

20  
21  
22  
23 **Seventh Claim for Relief**  
24 (Negligence of Fresh Express)

25 270. The Taylors incorporate the allegations in the preceding paragraphs as if fully set  
26 forth herein.

27 271. Fresh Express owed the Taylors a duty to use reasonable care in the growth,  
28 harvesting, manufacture, processing, distribution, marketing, and sale of its food products.

1           272. An ordinarily prudent grower, harvester, manufacturer, processor, distributor, and  
2 seller of salad products containing romaine lettuce and other produce, being fully aware of the  
3 risks of *E. coli* O157:H7, would not place a contaminated salad product on the market.

4           273. Fresh Express had reason to know, and in fact knew, that romaine lettuce grown  
5 in the Salinas, California growing region was grown in the vicinity of environmental hazards that  
6 posed an unreasonable risk of harm to consumers of leafy green products expected to be  
7 consumed raw.

8           274. Fresh Express had reason to know, and in fact knew, that in the fall of 2018, 2017,  
9 and 2016, the same outbreak strain contaminated romaine lettuce and other leafy greens grown in  
10 California, causing several multistate outbreaks and needless injury.

11           275. Fresh Express had reason to know, and in fact knew, that the romaine lettuce in  
12 the contaminated salad products that it grew, harvested, manufactured, processed, distributed,  
13 marketed, and sold had come from the Salinas, California growing region.

14           276. As a result of the knowledge alleged in the foregoing paragraphs, Fresh Express  
15 owed a duty to the Taylors, and other consumers similarly situated, to use reasonable care in the  
16 cultivation, harvesting, processing, manufacture, distribution, and sale of the adulterated salad  
17 product that caused the Taylor's injuries, which duties of care Fresh Express breached by, among  
18 other things, cultivating, harvesting, processing, manufacturing, distributing, and selling romaine  
19 lettuce grown in proximity to environmental hazards and failing to have in place pre- and post-  
20 harvest measures during processing sufficient to sanitize the lettuce and prevent cross-  
21 contamination.

22           277. Fresh Express had a duty to comply with all statutes, laws, regulations, standards,  
23 and safety codes pertaining to the cultivation, harvesting, processing, manufacture, distribution,  
24 storage, and sale of the salad product at issue.

1           278. Fresh Express had a duty to properly supervise, train, and monitor its employees,  
 2 and to ensure its employees comply with all applicable statutes, laws, regulations, standards, and  
 3 safety codes pertaining to the cultivation, harvesting, processing, manufacture, distribution,  
 4 storage, and sale of food products including the salad product at issue.

5           279. The Taylors are among the class of persons designed to be protected by the  
 6 statutes, laws, regulations, standards, safety codes, and provisions described above pertaining to  
 7 the cultivation, harvesting, processing, manufacture, distribution, storage, and sale of salad  
 8 product at issue.

9           280. Fresh Express breached its duties of care by the following acts and omissions,  
 10 among others:

- 11           a. Failing to comply with all statutes, laws, regulations, standards, and safety codes  
 12           pertaining to the cultivation, harvest, processing, manufacture, distribution,  
 13           storage, and sale of the salad product at issue;
- 14           b. Failing to adequately warn its customers of the risks of romaine lettuce produced  
 15           in the Salinas, California growing region;
- 16           c. Failing to properly select and screen produce suppliers to ensure the products it  
 17           received and resold were not adulterated with dangerous pathogens such as *E. coli*  
 18           O157:H7;
- 19           d. Failing to require adequate testing policies and procedures for its suppliers and  
 20           failing to adequately verify testing procedures;
- 21           e. Failure to maintain equipment, containers, and utensils used to process, convey,  
 22           hold, and store romaine lettuce in a manner that protects against contamination;
- 23           f. Failure to store romaine lettuce under conditions that would protect against  
 24           microbial contamination; and
- 25           g. Other acts and omissions as revealed through discovery.

26           281. As a direct and proximate result of the Fresh Express's acts and omissions of  
 27 negligence, the Taylors sustained injuries and damages in an amount to be proven at trial.  
 28

282. Fresh Express is therefore liable to the Taylors for all damages proximately caused by Fresh Express's negligence.

**Eighth Claim for Relief**  
(Negligence of Safeway)

283. The Taylors incorporate the allegations in the preceding paragraphs as if fully set forth herein.

284. Safeway owed the Taylors a duty to use reasonable care in the distribution, marketing, and sale of food products.

285. An ordinarily prudent distributor and seller of salad products containing romaine lettuce and other produce, being fully aware of the risks of *E. coli* O157:H7, would not place a contaminated salad product on the market.

286. Safeway had reason to know, and in fact knew, that romaine lettuce grown in the Salinas, California growing region was grown in the vicinity of environmental hazards that posed an unreasonable risk of harm to consumers of leafy green products expected to be consumed raw.

287. Safeway had reason to know, and in fact knew, that in the fall of 2018, 2017, and 2016, the same outbreak strain contaminated romaine lettuce and other leafy greens grown in California, causing several multistate outbreaks and needless injury.

288. Safeway had reason to know, and in fact knew, that the romaine lettuce in the contaminated salad products that it marketed, retailed and sold had come from the Salinas, California growing region.

289. As a result of the knowledge alleged in the foregoing paragraphs, Safeway owed a duty to the Taylors, and other consumers similarly situated, to use reasonable care in the distribution, marketing, and sale of the adulterated salad product that caused the Taylor's injuries, which duties of care Safeway breached by, among other things, distributing and selling romaine lettuce grown in proximity to environmental hazards and failing to have in place post-

1 harvest measures during processing sufficient to sanitize the lettuce and prevent cross-  
2 contamination.

3       290. Safeway had a duty to comply with all statutes, laws, regulations, standards, and  
4 safety codes pertaining to the distribution and sale of the salad product at issue.

5       291. Safeway had a duty to properly supervise, train, and monitor its employees, and to  
6 ensure its employees comply with all applicable statutes, laws, regulations, standards, and safety  
7 codes pertaining to the distribution, storage, and sale of food products including the salad  
8 product at issue.

9       292. The Taylors are among the class of persons designed to be protected by the  
10 statutes, laws, regulations, standards, safety codes, and provisions described above pertaining to  
11 the distribution, storage, and sale of salad product at issue.

12       293. Safeway breached this duty of care by the following acts and omissions, among  
13 others:

- 14       a. Failing to comply with all statutes, laws, regulations, standards, and safety codes  
15       pertaining to the distribution and sale of the salad product at issue;
- 16       b. Failing to adequately warn its in-store customers of the risks of romaine lettuce  
17       produced in the Salinas, California growing region;
- 18       c. Failing to properly select and screen product suppliers to ensure the products it  
19       received and resold were not adulterated with dangerous pathogens such as *E. coli*  
20       O157:H7;
- 21       d. Failing to require adequate testing policies and procedures for its suppliers and  
22       failing to adequately verify testing procedures;
- 23       e. Failure to store romaine lettuce under conditions that would protect against  
24       microbial contamination; and
- 25       f. Other acts and omissions as revealed through discovery.

26       294. As a direct and proximate result of Safeway's acts and omissions of negligence,  
27 the Taylors sustained injuries and damages in an amount to be proven at trial.  
28

295. Safeway is therefore liable to the Taylors for all damages proximately caused by Safeway's negligence.

**Ninth Claim for Relief**  
(Negligence Per Se of Fresh Express)

296. The Taylors incorporate the allegations in the preceding paragraphs as if fully set forth herein.

297. Fresh Express owed a duty to consumers, including the Taylors, to abide by all applicable state and federal statutes, laws, and regulations regarding food safety.

298. Fresh Express had a duty to comply with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and all of the rules, regulations, and policies promulgated pursuant to it. Fresh Express did not comply with these duties in its manufacturing, processing, distributing, and selling into interstate commerce of the romaine lettuce contaminated with *E. coli* O157:H7 to which the Taylors were exposed.

299. In particular, the romaine lettuce contaminated with *E. coli* O157:H7 that Fresh Express manufactured, processed, distributed, and sold into interstate commerce was adulterated under 21 C.F.R. Pt. 110, 21 C.F.R. Pt. 117, and 21 U.S.C. § 342 in violation of 21 U.S.C. § 331.

300. In violation of 21 U.S.C. § 350g, Fresh Express failed to identify, implement, and effectively monitor appropriate, adequate, and effective preventative controls to significantly minimize or prevent the occurrence of hazards that could affect the food it manufactured, processed, distributed, and sold, and to assure that such food was not adulterated.

301. Fresh Express's violations of the Federal Food, Drug, and Cosmetic Act include violations of the regulations adopted by the FDA. Among other violations, Fresh Express failed to implement and/or utilize adequate, appropriate, and effective processes and quality controls in violation of 21 C.F.R. § 110.80 and 21 C.F.R. § 117.80; failed to implement adequate, appropriate, and effective preventative controls in violation of 21 C.F.R. § 117.135; failed to

1 verify that preventative controls were consistently implemented and were effectively and  
2 significantly minimizing or preventing the hazards in violation of 21 C.F.R. § 117.165; and  
3 failed to implement a supply-chain program that assured that a hazard requiring a supply-chain-  
4 applied control had been significantly minimized or prevented in violation of 21 C.F.R. §  
5 117.410.

6  
7 302. Fresh Express's non-compliance with 21 U.S.C. § 350g and 21 C.F.R. Pt. 117,  
8 Subparts C and G were violations of 21 U.S.C. § 331(uu).

9 303. The California Health & Safety Code § 110620 makes it unlawful to manufacture,  
10 sell, deliver, hold, or offer for sale any food that is adulterated with dangerous bacteria, including  
11 *E. coli* O157:H7. Fresh Express manufactured, sold, delivered, held, and offered for sale a salad  
12 product that was adulterated with *E. coli* O157:H7, and therefore breached the duty to comply  
13 with this law.

14  
15 304. The fact that Fresh Express failed to comply with these statutes, laws, and  
16 regulations regarding food safety presumes that Fresh Express was negligent.

17 305. The Taylors were in the class of people intended to be protected by these statutes,  
18 laws, and regulations regarding food safety. Failure by Fresh Express to comply with these  
19 statutes, laws, and regulations was a direct and proximate cause of the Taylors' injuries.

20 306. Failure by Fresh Express to comply with these statutes, laws, and regulations was  
21 a substantial factor in bringing about the harm alleged herein.

22  
23 307. As a direct and proximate result of Fresh Express's acts and omissions of  
24 negligence per se, the Taylors sustained injuries and damages in an amount to be proven at trial.

25 308. Fresh Express is therefore liable to the Taylors for all damages proximately  
26 caused by Fresh Express's negligence per se.

**Tenth Claim for Relief**  
(Negligence Per Se of Safeway)

309. The Taylors incorporate the allegations in the preceding paragraphs as if fully set forth herein.

310. Safeway owed a duty to consumers, including the Taylors, to abide by all applicable state and federal statutes, laws, and regulations regarding food safety.

311. Safeway had a duty to comply with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and all of the rules, regulations, and policies promulgated pursuant to it. Safeway did not comply with these duties in its distributing, marketing, and selling into interstate commerce of the romaine lettuce contaminated with *E. coli* O157:H7 to which the Taylors were exposed.

312. In particular, the romaine lettuce contaminated with *E. coli* O157:H7 that Safeway distributed, marketed, and sold into interstate commerce was adulterated under 21 U.S.C. § 342 in violation of 21 U.S.C. § 331.

313. The California Health & Safety Code § 110620 makes it unlawful to manufacture, sell, deliver, hold, or offer for sale any food that is adulterated with dangerous bacteria, including *E. coli* O157:H7. Safeway sold, delivered, held, and offered for sale a salad product that was adulterated with *E. coli* O157:H7, and therefore breached the duty to comply with this law.

314. The fact that Safeway failed to comply with these statutes, laws, and regulations regarding food safety presumes that Safeway was negligent.

315. The Taylors were in the class of people intended to be protected by these statutes, laws, and regulations regarding food safety. Failure by Safeway to comply with these statutes, laws, and regulations was a direct and proximate cause of the Taylors' injuries.

316. Failure by Safeway to comply with these statutes, laws, and regulations was a substantial factor in bringing about the harm alleged herein.





- a. Defendants engaged in unconscionable commercial practices, through deception, fraud, and making false promises and misrepresentations, including, but not limited to, marketing and promoting adulterated food products and Defendants' practices as safe and as otherwise providing benefits as detailed in this Complaint without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.
- b. Defendants used and employed deception, fraud, false pretenses, false promise, and misrepresentation in the following manner:
  - i. Failing to disclose knowledge of the hazards and risks posed by growing and processing romaine lettuce in the Salinas, California growing region, including, but not limited to, the hazards and risks posed by nearby environmental risk factors;
  - ii. Failing to disclose knowledge of the hazards and risks associated with adulterated salad products such as the product at issue, including, but not limited to, repeated contamination by the same STEC strain in three preceding years; and
  - iii. Downplaying and understating the health hazards and risks associated with the use of the Defendants' food products.
- c. In connection with the sale, advertisement, and marketing of the adulterated food products, Defendants engaged in knowing concealment, suppression, and omission of material facts regarding the risks and hazards created by the methods used by Defendants and their suppliers, including, but not limited to, their use of unsafe and unsanitary agricultural water.

328. The aforesaid promotion and release of the adulterated romaine lettuce, salad product, and produce into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or the knowing concealment, suppression, or omission in connection with the sale or advertisement of such merchandise by Defendants in violation of the CLRA.

329. Had the Taylors known of the dangers associated with the salad product at issue, they would not have purchased or consumed it.

330. As a direct result of Defendants' misrepresentation, concealment, and suppression of facts relating to the dangers associated with the salad product they sold, the Taylors suffered

1 the injuries and damages described herein.

2 331. As a further and direct result of Defendants' misrepresentation, concealment, and  
3 suppression of facts, the Taylors are entitled to punitive damages, attorneys' fees and costs, and  
4 any other relief the Court deems proper.

5  
6 **Twelfth Claim for Relief**  
(Punitive Damages)

7 332. The Taylors repeat and reallege each and every allegation set forth above with the  
8 same force and effect as if set forth fully herein.

9 333. At all times relevant hereto, it was highly likely that serious harm would arise  
10 from Defendants' conduct as alleged above.

11 334. Defendants knew that their practices as alleged above would likely cause another  
12 pathogenic outbreak and resulting serious illnesses and/or deaths.

13 335. Upon learning that their practices would likely cause serious harm, Defendants  
14 failed and refused to take reasonable and effective corrective action.

15 336. Despite their knowledge of the likelihood of serious harm, Defendants continued  
16 their dangerous practices—including but not limited to their conduct in passing along dangerous  
17 products, the quality and safety of which Defendants took no meaningful effort to ensure—with  
18 wanton and willful disregard of persons who foreseeably might be harmed.

19 337. The Defendants knew they were recklessly disregarding the likelihood that  
20 serious harm that would result from their practices.

21 338. Defendants conduct was carried on with willful and conscious disregard of the  
22 rights or safety of others.

23 339. Under California Civil Code § 3294, Defendants are liable for punitive damages.  
24  
25  
26  
27  
28

**Request for Relief**

WHEREFORE, the Plaintiffs requests judgment against Defendants as follows:

340. For compensatory damages, including but not limited to past and future physical and emotional injury, permanent disability, past and future medical costs and expenses, past and future physical and mental pain and suffering, past and future discomfort and loss of enjoyment of life, lost the love, care, affection, companionship, and other pleasures of the family relationship, past and future wage loss, loss of earning capacity, and other damages, the exact amount to be proven at trial;

341. For punitive and/or exemplary damages for the damages in an amount to be determined at trial;

342. For statutory, treble damages and penalties;

343. For pre- and post-judgment interest on the above-stated amounts;

344. For costs of suit incurred herein;

345. For reasonable attorneys' fees and costs under the CLRA;

346. For such other and further relief as the Court deems just and proper; and

347. For the opportunity to amend or modify the provisions of this Complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served.

**Demand for Jury Trial**

Plaintiffs hereby requests a jury trial on all issues raised in this Complaint.

Dated:

By:

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1 and

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